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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/300,510	09/02/1994	MALCOLM L. GEFTER	092.0US	5007

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EXAMINER
SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
1644	42

DATE MAILED: 08/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s) GRETER et al
	Examiner SAUNDERS	Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 6/4/03.

☑ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☑ Claim(s) 108-109, 114-117, 120-123, 128-138 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☑ Claim(s) 108-109, 114-117, 120-123, 128-133, 136, 138 is/are rejected.

☑ Claim(s) 134-135, 137 is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other_____

Office Acti n Summary

Amendment of 6/4/03 has been entered. Claims 108-109, 114-117, 120-123 and 128-138 are pending and under examination.

The amendment has entered no new matter.

Regarding 112 rejections of record, note. The following are maintained:

Claim 117 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 117 contains new matter by reciting "about" before the percentage value. Specification page 14 does not support "about".

Regarding prior art rejections of record, the 103 rejection over Briner et al. has been withdrawn. These authors fail to teach the features recited in amended claim 108.

The 102 and 103 rejections based upon Gefter et al. (WO93/9178) are maintained or newly stated as follows.

Claims 108-109, 114-117, 120-123, 128-133 and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gefter et al. (WO93/1978) in light of Briner et al.

The rejection of record under 102 has been stated previously (paper 39, page 11).

Applicant considers that the rejection based upon 102 Gefter et al. has been overcome by introducing language into claim 108 regarding a "T cell stimulation index".

The amendment has overcome anticipation but does not overcome obviousness,

since Gefter et al. clearly teach the therapeutic use of peptides which have a T cell stimulation index of a least 3.5 at pages 14 and 18.

Regarding the "positively index" Gefter et al. do not recite this term; however, they use the term "PI" at page 63. Therein "PI" is defined in the same Mathematical manner as applicant instantly defines "positivity index" at page 10. The Table of Gefter et al. at pages 62-63 shows numerous fel-d peptides having a "PI" of greater than 150. Gefter et al. also teach (page 32) that one should select a peptide having a sufficient number of epitopes such that a substantial percentage of a population of individuals sensitive to the antigen may be treated. Since the PI defined by Gefter et al. page 63 reflects the percentage of individuals that show positivity responses (as measured by a T-cell stimulation index) it would have been obvious to set a lower limit upon the "PI", to assure that a substantial portion of individuals may be effectively treated. The value of "150" appears to have been arbitrarily disclosed by applicant instantly. It is to be noted, however, that no peptide in the Table of Gefter et al. has a PI below 150 (the lowest, Fel-d 4-3, has a PI of 185). Also the examiner finds nothing remarkable about the figure "150" from applicant's disclosure; there is no experimental data to support the notion that this limit serves as a cut-off point that defines therapeutically useful peptides versus non useful peptides.

The teachings of Gefter et al. with a respect not the dependent claims, under anticipation or obviousness. Have bee previously noted (paper 39, page 11).

Claims 108-109, 114-117, 120-123, 128-133 and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gefter et al. in light of Briner et al. and in view of Griffith et al. (5,710,126 newly cited).

The 103 rejections over Gefter et al. in light of Briner et al. have been stated supra. Lest applicant consider that Gefter et al. do not teach sufficiently to motivate one to select therapeutic peptides according to a "positively index", the examiner will rely upon Griffith et al.

Griffith et al. teach (cols. 12-13) that it was known to select therapeutic peptides according to both a stimulation index and a positivity index. The instantly recited figure of "150" for the positively index is within the range taught (col. 13, lines 6-9). Applicant has no data demonstrating that "150" is better than "100" or "200" taught by Griffiths et al.

103 rejections based on Rogers et al. (WO93/08200 or U.S. 5,547,669) are newly stated as follows.

Claims 108, 114-115, 120-123, 129, 131, 133 and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al., as evidenced by Briner et al., and in view of Griffith et al. (newly cited).

The 102 rejection over Rogers et al., as evidenced by Briner et al. has been stated previously (Paper 39, pages 9-10).

Applicant considers that the rejection based upon Rogers et al. has been overcome by introducing language into claim 108 regarding a "T cell stimulation index" and a "positivity index".

The amendment has overcome anticipation but does not render the claims unobvious. The Rogers et al. clearly teach the therapeutic use of peptides, which have a T cell stimulation index of a least 3.5 at cols. 9 and 10.

With respect to the recited "positivity index", the examiner has noted supra that Griffith et al. teach (cols. 12-13) that it was known to select therapeutic peptides according to both a stimulation index positivity index. The examiner has discussed supra how one would have been motivated to include a positivity index as one of the criteria for peptide selection, because this index reflects the percentage of the population which is responsive to T-cell epitopes in the peptide. The examiner has also argued supra that the recited value of "150" is merely arbitrary.

From the above, it is seen that the amendment has merely added features to claim 108 that reflect selection criteria that were known and obvious.

The teachings of Rogers et al. regarding various dependent claims presently rejected have been noted in Paper 39 at pages 9-10.

Claim 136 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gefter et al. in light of Briner et al. as applied to claim 108 above, and further in view of Litwin et al.

Claim 136 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gefter et al. in light of Briner et al. and in view of Griffith et al. as applied to claim108 above, and further in view of Litwin et al.

Claim 136 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. in light of Briner et al. and in view of Griffith et al. as applied to claim108 above, and further in view of Litwin et al.

Teachings of Litwin et al. regarding the gradual increasing of dose of the administered peptide(s) have been previously noted (paper 39, page 12). Since claim 108 remains obvious so does claim 136, with the teachings of Litwin et al.

Since no 102 (a), (b) or (e) rejection of record remains, the previously stated rejection under 102 (F) has been withdrawn.

Applicant's urgings filed 6/4/03 have been considered but are unconvincing of patentability.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-4718. The examiner can normally be reached on (703) 308-3976 from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644

D.Saunders:jmr
August 25, 2003